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K001167

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

The following summary is provided pursuant to Section 513(I)(3)(A) of the Federal Food, Drug, and Cosmetic Act.

A. Applicant Information

- ***Submitter:*** Orthomerica Products, Inc. 505 31st Street, P.O. Box 2927, Newport Beach, CA 92659, FDA Establishment Registration Number 1058152

- ***Contact:*** David C. Kerr, Chief Executive Officer, Telephone: (949) 723-4500, Facsimile: (949) 723-4501; Shannon R. Schwenn, Vice President, Manufacturing, Telephone: (407) 290-6592, Facsimile: (407) 290-2419

- ***Summary Date:*** April 6, 2000

B. Device Name and Classification

- ***Proprietary Name:*** OPI Band

- ***Common or Usual Name:*** Cranial Orthosis

- ***Classification Name:*** Cranial Orthosis

- ***Predicate Device:*** DOC™ Band, Cranial Orthosis, K964992, classified under 21 CFR § 882.5970.

C. Device Description

The OPI Band is a cranial orthosis used to treat abnormal head shape (clinically referred to as positional or deformational plagiocephaly) in infants ages 3 to 18 months. The orthosis applies mild pressure to the protruding areas of deformity and leaves room for growth in those areas of the infant's head that were flattened during deformation. The OPI Band is available only if prescribed by a physician.

The orthosis is custom made for each patient from a mold of the infant's head initially prepared by the treating clinician. The mold is then sent to Orthomerica where it is used to create the orthosis. Each orthosis is comprised of a an outer shell of plastic, an inner shell of foam, a strap and buckle for securing the orthosis, and a bellows mechanism for safety. The treating clinician modifies the orthosis for a precise fit, and monitors its use to ensure that no severe adverse reactions occur.

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D. Intended Use

The OPI Band is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic- and brachycephalic-shaped heads.

E. Comparison to Predicate Device

The OPI Band and its predicate device are very similar with respect to production, instructions for use, materials, safety and effectiveness, and special controls. The most significant difference between the two products is that the OPI Band is equipped with a bellows safety feature to ensure that inappropriate levels of pressure are not exerted on the infant's head. The bellows is formed from materials already used in both orthoses, however, and therefore does not present new safety concerns.

The proposed indications for the OPI Band are a subset of those claimed by the predicate device. Whereas the predicate device is indicated for treating scaphocephalic-shaped heads, the OPI Band is not. In all other respects the indications for use are identical for both orthoses.

F. Performance Data

The effectiveness of the OPI Band has been established by numerous studies. Researchers studying the effects of treatment with cranial orthoses on infants have concluded that the devices are effective in correcting abnormal headshape, without evidence of relapse following treatment. In addition, treatment with cranial orthoses is reported to improve the results of surgery in severe cases to such a degree that an ordinarily necessary additional surgical treatment can be avoided. The most comprehensive assessment of cranial orthoses monitored the treatment of more than 750 infants over a span of nearly ten years. Results were recorded at the end of the treatment period and again at 12, 18, and 24 month follow-ups. The study documented complete or near complete correction of asymmetry for a wide variety of head shapes.

The safety of the cranial orthoses is established under standard biocompatability assessments and other tests. The biocompatability assessments reveal that the device is not expected to adversely affect infants under intended conditions of wear. Specifically, the materials used in the device are not reported to cause skin irritation or any toxic harms. In addition, the product is designed to avoid improper slippage or harmful levels of pressure. The device lining is smooth and does not pose threats of agitation or abrasion.

The safety and effectiveness of the OPI Band was confirmed to be substantially equivalent to the predicate devices through a bench test comparison of the pressure exerted by the device on an infant's head, and potential slippage of the devices under intended conditions of use. The bench test examined the performance of both devices

under identical test scenarios. In each case, the devices were observed to perform almost uniformly, with minor differences in performance attributed to inconsistencies in the positioning of the device on the test mold and to the high sensitivity of the testing equipment.

G. Summary

The safety and effectiveness data submitted to FDA establishes that OPI Band is safe and effective for its intended use and is substantially equivalent to applicable predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2000

Orthopedic Products, Inc.
c/o Mr. William H. E. von Oehsen
Powell, Goldstein, Frazer & Murphy LLP
1001 Pennsylvania Avenue N.W., Sixth Floor
Washington, D.C. 20004

Re: K001167
Trade Name: OPI Band
Regulatory Class: II
Product Code: MVA
Dated: April 7, 2000
Received: April 10, 2000

Dear Mr. Von Oehsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Vochmer.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1b

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510(k) Number (if known): K001167

Device Name: OPI BAND

Indications For Use:

The OPI Band is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic- and brachycephalic-shaped heads.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001167

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)